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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 662,254	09 14 2000	Richard W. Moyer	UF-221C1XC1	2442

23557 7590 04 24 2002

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EXAMINER

BECKERLEG, ANNE M

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/24/2002

LD

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,254

Applicant(s)

MOYER ET AL.

Examiner

Anne M Beckerleg

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2002 and 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-90 and 92-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-90 and 92-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

Applicant's amendments received on 1/24/02 and 2/11/02, and the declaration under 1.132 received on 2/11/02 have been entered. Claim 91 has been canceled. Claims 76-90 and 92-102 are pending in the instant application.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Double Patenting

The rejection of claims 90-102 for obviousness-type double patenting over U.S. Patent No. 6,127,172 is withdrawn in view of the cancellation of claim 91 and the applicant's submission of a terminal disclaimer.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1632

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 76-78, 81, and 83-89 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-21 of U.S. Patent No. 6,106,825, 8/22/00, hereafter referred to the '825 patent. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. The claims of the '825 patent are both broader and narrower than the instant claims. The '825 claims recite methods for delivering a heterologous gene to a vertebrate cell comprising contacting the cell with a recombinant entomopox virus (rEPV) encoding a heterologous gene operatively linked to a early vaccinia virus promoter, wherein the contacting occurs in vitro or in vivo. Instant claim 76 recites methods for delivering a polynucleotide encoding a protein to a vertebrate cell comprising introducing into the cell an rEPV comprising the polynucleotide encoding the protein operably linked to a heterologous early pox promoter. Claims 86-87 recite that the introduction occurs either in vitro or in vivo. Thus, the '825 claims represent a species of the instant claims in that an early vaccinia virus promoter is an early pox virus promoter. It is well established that a species of a claimed invention renders the genus obvious. In re Schaumann , 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

Art Unit: 1632

The '825 claims are also broader than the instant claims in that they do not specifically recite the limitations of instant claims 77-78, 81, 83-85, and 88-89. However, these limitations are clearly taught as preferred embodiments of the methods claimed in the '825 patent in columns 7-9, 14-15, and 16. Thus, by specifically claiming the same methods as the instant claims, and by teaching all of the specific limitations recited by the instant claims, the claims of the '825 patent render claims 76-78, 81, and 83-89 obvious.

Claim Rejections - 35 USC § 112

The rejection of claims 76-102 under 35 U.S.C. 112, first paragraph, is maintained over claims 76-89. Applicant's arguments and the declaration by Dr. Moyer have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant's claims have been amended to recite that the methods for delivering a polynucleotide encoding a protein to vertebrate cells either *in vitro* or *in vivo* comprise introducing into the cells an rEPV comprising the polynucleotide operatively linked to an early pox virus promoter or a non-pox virus promoter.

The previous office action stated that the specification does not provide an enabling disclosure for the *in vivo* delivery of therapeutically effective recombinant entomopox viruses or vectors to animals. The applicant argues that a "therapeutic effect" is not recited by the instant

Art Unit: 1632

claims and that both early pox virus promoters and non-pox virus promoters can be utilized in rEPV vectors to deliver genes encoding proteins to a cell in vivo. Based on applicant's arguments and the working examples provided in the specification, the office acknowledges that the claims are enabled for the **non-therapeutic** delivery of polynucleotides encoding a protein to vertebrate cells in vivo using the disclosed rEPV wherein the polynucleotide encoding the protein is operably linked to an **early pox virus** promoter.

Applicant's arguments have not been found persuasive in regards to the use of a non-pox virus promoter to express proteins of interest in vivo. The declaration by Dr. Moyer states that pages 75 and 81 of the instant specification demonstrate that non-pox virus promoters such as the CMV promoter and TK promoter can be used to express a heterologous selectable marker from rEPV in mammalian cells in vitro. Page 75 of the instant specification teaches how to construct an rEPV comprising CMV and TK promoters operably linked to marker genes. Page 85 of the specification teaches that the rEPV disclosed on page 75 can infect cells in vitro and that after multiple rounds of selection, cells expressing both marker genes can be detected. Expression from non-poxvirus promoters requires the participation of cell based factors rather than entomopox factors, as such, both the specification and the art teach that expression using promoters such as CMV or HSV-TK requires the integration of the recombinant EPV DNA into the host cell's genome such that it is accessible to host transcription factors. The applicant's data clearly demonstrates that integration following infection with rEPV is not a high percentage event such that detection of cells which may express the recombinant protein of interest requires several

Art Unit: 1632

rounds of selection to increase the number of cells with the integrated DNA. The specification fails to provide sufficient guidance as to dosages or routes of administration of rEPV which utilize non-pox virus promoters to vertebrates such that rEPV dna integrates into the host's cells in vivo and results in detectable amounts of protein expression. Further, the specification does not provide any guidance as to methods of selecting for cells with integrated EPV dna in vivo such that the expression of the heterologous gene can be detected in vivo. Thus, based on the mechanism of expression of a heterologous gene from an rEPV using a non-pox virus promoter, the lack of guidance provided by the specification for dosages, routes of delivery, and selection methods for expressing detectable amounts of protein in vivo by administering rEPV encoding a heterologous protein under transcriptional control of any non-pox virus promoter, and the breadth of the claims, it would have required undue experimentation to practice the scope of the instant invention as claimed.

Claim Rejections - 35 USC § 102

The rejection of claims 90, 92, 95, 97, and 100-102 under 35 U.S.C. 102(b) as being anticipated by Li et al. is withdrawn in view of applicant's amendment to the claims to recite non-pox virus promoters.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1632

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 90, 92, 95, 97, and 99-102 are newly rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,762,924, 6/9/98, hereafter referred to as Dall et al. The applicant claims entomopox vectors comprising a polynucleotide encoding a protein operably linked to a non-pox virus promoter, and cells infected with said vectors. The applicant further claims said vectors wherein the protein is an interferon or growth factor.

Dall et al. teaches entomopoxvirus vectors and viruses comprising a heterologous DNA selected from a group including interferons, and human growth hormone, and cells infected with the recombinant viruses (Dall et al., column 21-22, claims 1-28). Dall et al. further teaches that the heterologous DNA is expressed using the heterologous gene's natural promoter (Dall et al., column 3, lines 30-39). Thus, by teaching all the limitations of the claims as written, Dall et al. anticipates the invention as claimed.

Oath/Declaration

The office acknowledges the copies of the executed oath and declaration received on 1/24/02.

Art Unit: 1632

Claims 93-94, 96, and 98 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Beckerleg

A handwritten signature in black ink, appearing to read 'Dr. A.M.S. Beckerleg', with a long horizontal stroke extending to the right.